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August 23, 2023

Honorable Michael A. Shipp, U.S.D.J.  
United States District Court  
Clarkson S. Fisher Building & US Courthouse  
402 East State Street  
Trenton, NJ 08608

Re: *Johnson & Johnson Talcum Powder Products, Marketing, Sales Practices and Products Liability Litigation*  
**Case No.: 3:16-md-02738-MAS-RLS**

Dear Judge Shipp:

The parties have been unable to agree on what paragraph 8 of the proposed scheduling order should state. The defendants believe that the language should be substantially the same as was in the original Order entered by Chief Judge Wolfson on June 1, 2021 [Dkt. 22100], namely:

Dispositive motions, including *Daubert* motions, shall be filed by  
**May 6, 2024.**

The Plaintiffs propose instead:

Dispositive motions, including any *Daubert* motions relating to case-specific and general expert opinions not previously addressed by the Court's April 27, 2020 *Daubert* opinion, shall be filed by **May 6, 2024.**

The Plaintiffs' language would prohibit Your Honor and the parties from raising any general causation arguments with regard to the experts in the upcoming trials. This is inconsistent with the law, the facts, commonsense and perhaps most importantly, Chief Judge Wolfson's opinion itself.

Here is what Chief Judge Wolfson wrote in her April 27, 2020 opinion:

**[S]tudies continue to be conducted by the scientific community. In fact, during the pendency of these motions, the parties have updated the Court with a number of studies that have been recently released on this topic.** Those submissions, however, do not alter the Court's *Daubert* analyses in this Opinion, since the parties have not requested leave to supplement any expert reports based on newly published studies. Rather, because the experts who are the subject of these *Daubert* motions did not review the newly-released studies in forming their expert opinions challenged here, **I will not consider those studies**

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**for the purpose of resolving the pending motions. However, this does not foreclose the possibility that the parties may seek leave from the Court to supplement an expert's report based on any new and relevant studies. And, indeed, if such supplemental reports impact my *Daubert* decisions made in this Opinion, I may amend my rulings at a later time.**

Dkt. 13186 at 4 n.6 (emphasis added).

And the science has changed over the last three years. For example, one of the studies that Judge Wolfson's opinion did not consider was a pooled analysis of data for 252,745 women, led by scientists at the National Institute of Environmental Health Sciences and published in the Journal of the American Medical Association, concluding that "there was not a statistically significant association between use of powder in the genital area and incident ovarian cancer." Katie M. O'Brien et al., *Association of Powder Use in the Genital Area with Risk of Ovarian Cancer*, 323 JAMA 49, 49 (2020), available at <https://jamanetwork.com/journals/jama/fullarticle/2758452>. Each of the plaintiff experts who have addressed epidemiology and causation in Stage Three cases has discussed the O'Brien article, which was also explored at their Stage Three depositions. Chief Judge Wolfson did not consider the O'Brien study, and others like it, in her April 27, 2020 order, but she expressly left open the possibility that she would amend her rulings in the future based on that sort of information. Defendants urge the Court not to accord Chief Judge Wolfson's *Daubert* conclusions any more finality than she herself accorded them.

It is no surprise, then, that the PSC seeks to preserve Chief Judge Wolfson's April 27, 2020 order to the extent possible. They want her order on general causation to stand for all of time so that they never need to wrestle with Dr. O'Brien's study of over a quarter of a million women, published in one of the most prestigious journals in the world, finding no statistically significant correlation between talcum powder use and ovarian cancer incidence. But if this Court accommodates the PSC's request to treat Chief Judge Wolfson's order as untouchable, it will be doing more than just ignoring the O'Brien study. It has already been over three years since Chief Judge Wolfson's order itself. The *Daubert* hearing that preceded the order occurred in July 2019 – more than four years ago. The order addressed expert opinions set out in reports served in late 2018 – nearly five years ago. And the parties do not presently contemplate filing *Daubert* motions in Stage Three cases until May 2024 – over five and a half years after the opinions addressed by Judge Wolfson's April 27, 2020 order were finalized. A trial date will obviously follow some time thereafter. Granting the PSC's request and prohibiting future *Daubert* motions from addressing issues that Chief Judge Wolfson's order addressed would mean that the next bellwether trial in this MDL will completely ignore the most recent **six years** of science on the issue.

This is to say nothing of the administrative nightmare that the Court would encounter in trying to police the limitation the PSC requests. Chief Judge Wolfson's April 27, 2020 opinion [Dkt. 13186] was 141 pages long. Enabling the parties to object to future *Daubert* arguments solely because they arguably overlap with one or more of those 141 pages will simply create a sideshow that the Court does not need. By way of example only: the April 27, 2020 order did not address specific causation as to any of the Stage Three cases. However, specific causation in those cases will rest on differential diagnoses that implicate general causation, which was addressed (based on outdated science) in Chief Judge Wolfson's order. Defendants have not yet served expert reports for the Stage Three cases; if Defendants' specific causation experts choose not to rule in talcum powder as a potential cause for an individual plaintiff's ovarian cancer on the basis that it is not a risk factor (i.e., that science does not support general causation), will they be required to base

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that decision solely on literature that Chief Judge Wolfson considered years ago lest Defendants be accused of relitigating the April 27, 2020 order? The lack of bright-line rules would inevitably shift the Court's attention away from the Federal Rules of Evidence that should guide the inquiry and toward a years-old opinion that was never intended to be etched in stone, even by its author.

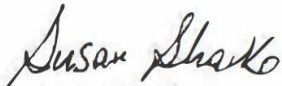
And – it's not only the science that has evolved. The law has changed, too. Federal Rule of Evidence 702 was amended and will become effective this December, well before briefing will occur on these motions.

Defendants have not decided how they will proceed in the future with regard to which opinions they will challenge, but they ask that a scheduling order not handcuff them and prevent them from raising *Daubert* arguments to the Court.

For these reasons, Defendants request that the Court refrain from prohibiting *Daubert* arguments on issues that were addressed in Chief Judge Wolfson's April 27, 2020 *Daubert* order and opinion and adopt the Defendants' proposed language. Defendants' proposed Amended Stage Three Discovery Schedule, which differs from the agreed language only as to Paragraph 8, is submitted as Exhibit A to this letter.

Thank you for your consideration of these matters.

Respectfully,

A handwritten signature in black ink that reads "Susan Sharko". The signature is written in a cursive, flowing style.

Susan M. Sharko

SMS/emf

cc: Hon. Joel Schneider, U.S.M.J. (ret.) (via email)  
The Plaintiffs' Steering Committee (via email)  
All Counsel (via ECF)